

## REMARKS

Claims 1-3, 5, 20, 22, 24, 26 and 27 are presently pending in the application. Applicant gratefully acknowledges the allowance of method claims 20, 22, and 24 at page 2 of the instant Office Action.

Claims 1-3, 5, 26 and 27 stand rejected as lacking written description under 35 U.S.C. § 112, first paragraph. The Examiner believes that the claimed composition including a curing inhibitor is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the invention. The Examiner believes that the presence of a curing inhibitor in the composition calls into question the claimed curing characteristics. Applicants respectfully traverse the Examiner's rejection.

The first paragraph of 35 U.S.C. § 112 requires that the specification provide a written description of the claimed invention:

[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The purpose of the written description requirement is to ensure that the specification conveys to those skilled in the art that the applicants possessed the claimed subject matter as of the filing date sought. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). Regarding original claims, “[t]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.” MPEP 2163 IA citing *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976).

Applicants respectfully submit that one of ordinary skill in the art would readily understand that the inventors were in possession of the curable compositions of the present invention including a curing inhibitor. The Examiner has provided no evidence to the contrary.

The language of claim 1 is expressly provided in the specification as originally filed. At page 13 lines 25-27, the specification expressly states that “a composition may comprise one or more additives, e.g. one or more additives selected from the group consisting of contrast agents, curing inhibitors and chain extenders.” The composition, of course, is described at page 4 lines 9-16 as a “biocompatible polymer composition . . . comprising a matrix pre-polymer, a filler, and a curing agent, wherein said composition has a viscosity at 25 °C, as measured by a Brookfield viscosimeter of 2 000 to 12 000 cSt which biocompatible polymer composition is curable in the presence of a curing catalyst at 37 °C to form a cured material with an elongation until rupture of at least 5 % and an elastic modulus of at least 1 MPa.” The specification expressly describes a curable composition as claimed that includes a curing inhibitor. Accordingly, there should be no doubt that one of skill in the art would readily understand that applicants were in possession of the claimed invention at the time the application was originally filed.

Also, the language of claim 1 is expressly found in originally filed claims 1 and 7. Accordingly, under MPEP 2163 and *In re Wertheim*, there is a strong presumption of adequate written description. In order to rebut the presumption, the Examiner “has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.” *In re Wertheim*, 541 F.2d at 263. Applicants respectfully submit that the Examiner has not presented any evidence of why one of skill in the art would not recognize in the disclosure a description of the invention defined

by the claims. In view of the express language in the specification and the originally filed claims, the Applicants respectfully submit that no such evidence exists.

To the extent the Examiner is concerned about how a composition that includes a curing inhibitor can nonetheless be curable, applicants respectfully note that at page 14 lines 12-15, the specification describes that “[c]uring inhibitors may be present in the composition to improve stability of the composition until the curing is induced, shortly before application of the composition. An examples of a curing inhibitors is 1,3,5,7-tetravinyl-1,3,5,7-tetramethylcyclotetrasiloxane.” One of skill in the art would readily understand that curing inhibitors improve stability of the composition by inhibiting curing until curing is desired.

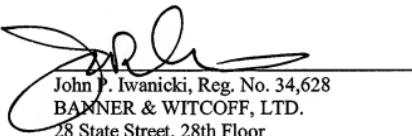
The presence of a curing inhibitor in a composition to be cured is not inconsistent given the written description of the invention in the specification as understood by one of skill in the art. Applicants respectfully note that the claim is to a curing inhibitor, not a curing prohibitor. The Examiner seems to think that a presence of a curing inhibitor in a composition prohibits all curing. This is clearly not the case with Applicants’ invention. This understanding is supported insofar as immediately after the paragraph describing the use of curing inhibitors, the specification further describes that “[t]he curing may be initiated and propagated in any way suitable to cure the particular combination of matrix pre-polymer and curing agent as long as this curing is physiological acceptable. The curing may for example be started under influence of radiation, e.g. electromagnetic radiation or chemically, e.g. by an added catalyst or reactant or by a component that is naturally present in the body, e.g. water or particular ions.” Clearly, the specification describes that curing of the composition may be initiated by one or more of the different modes of initiation, even where a curing inhibitor is present. A selected mode of initiation, and curing of the composition, need have no relation to the curing inhibitor or the

stability provided to the composition before curing is initiated. For example, a curing inhibitor provides stability to the composition by inhibiting photo-initiated curing while the composition is being administered, and then curing of the composition can be initiated by a curing catalyst at elevated temperatures.

Having addressed all outstanding issues, Applicants request that a Notice of Allowance be issued in the above-referenced application. The Commissioner is authorized to apply any additional charges or credits to Deposit Account No. 19-0733.

Respectfully submitted,

Dated: July 20, 2009



John P. Iwanicki, Reg. No. 34,628  
BANNER & WITCOFF, LTD.  
28 State Street, 28th Floor  
Boston, MA 02109  
(617) 720-9600